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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/657,407

09/08/2003

Tom Barber

DI-5802

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29200

7590

06/16/2005

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EXAMINER

JACKSON, ANDRE K

ART UNIT

PAPER NUMBER

2856

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

EX

<b>Office Action Summary</b>	<b>Application No.</b> 10/657,407	<b>Applicant(s)</b> BARBER ET AL.	
	<b>Examiner</b> André K. Jackson	<b>Art Unit</b> 2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-52 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41-49 is/are allowed.
- 6) ☒ Claim(s) 1-8, 20, 22, 30 and 31 is/are rejected.
- 7) ☒ Claim(s) 9-19, 21, 23-29, 32-40 and 50-52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                   |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

## DETAILED ACTION

### *Claim Objections*

1. Claims 50-52 are objected to because of the following informalities:

Regarding claim 50, in line 5 of the claim there seems to be a word added or missing. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Mihashi.

Regarding claim 22, Mihashi discloses a solution including physiologically safe particles; a device that creates an aerosol from the solution; and where the aerosol is injected inside the hollow fibers and a particle counter counts particles flowing through at least one of the fiber walls (Abstract).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3,5,7,8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mihashi in view of Folden et al (WO9711771).

Regarding claim 1, Mihashi discloses in the Japanese patent entitled "Leak testing method for hollow fiber membrane module" a device for injecting physiologically safe particles into a lumen of each of at least a majority of the fibers, and a particle counter that counts particles that escape through the fiber walls (Abstract). Mihashi does not disclose injecting various sized particles into a lumen and where at least a majority of the particles are too large to pass through a majority of the pores of the walls. However, Folden et al. (WO9711771) disclose injecting various sized particles into a lumen and where at least a majority of the particles are too large to pass through a majority of the pores of the walls (Figure 1; Pages 1,2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mihashi to include

injecting various sized particles into a lumen and where at least a majority of the particles are too large to pass through a majority of the pores of the walls. By adding this feature the apparatus would be able to determine the membranes efficiency.

Regarding Claim 2, Mihashi do not disclose a pressurized fluid, wherein the device combines the variously sized particles with the fluid. However, Folden et al. (WO9711771) disclose a pressurized fluid, wherein the device combines the variously sized particles with the fluid (Figure 1; Pages 1,2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mihashi to include a pressurized fluid, wherein the device combines the variously sized particles with the fluid. By adding this feature the apparatus would be able to determine the membranes efficiency.

Regarding claim 3, Mihashi disclose where the pressurized fluid includes pressurized air (Abstract).

Regarding claim 5, Mihashi does not disclose a liquid initially entraining the particles. However, Folden et al. includes a liquid initially entraining the particles (Figure 1). Therefore, it would been obvious to one of ordinary skill in the art at the time the invention was made to modify Mihashi et al. to include a liquid initially entraining the particles. By adding

this feature the apparatus would be able to transfer the particles to the membrane.

Regarding claim 7, Mihashi does not disclose at least one device for removing vapor from the particles before the particles enter the dialyzer. However, Folden et al. disclose at least one device for removing vapor from the particles before the particles enter the dialyzer (heater). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mihashi to include at least one device for removing vapor from the particles before the particles enter the dialyzer. By adding this feature the apparatus would be able to heat the fluid to body temperature.

Regarding claim 8, Mihashi does not disclose where the moisture removing device is selected from the group consisting of: a heater and a chemical drying device. However, Folden et al. disclose where the moisture removing device is selected from the group consisting of: a heater and a chemical drying device (heater). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mihashi to include where the moisture removing device is selected from the group consisting of: a heater and a chemical drying device. By adding this feature the apparatus would be able to heat the fluid to body temperature.

Regarding claim 20, Mihashi discloses which includes a plurality of flow lines extending from the dialyzer to the particle counter (Figure).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mihashi in view of Folden et al. and in further view of Wadsworth et al.

Regarding claim 4, Mihashi do not disclose where the particles are NaCl. However, Wadsworth et al. disclose in the patent entitled "Method for testing filtration efficiency" where the particles are NaCl (Column 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mihashi to include where the particles are NaCl. By adding this feature the apparatus would be able to test the efficiency of the media with an aerosol which has particular properties.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mihashi in view of Folden et al. and in further view of Hara et al.

Regarding claim 6, Mihashi does not disclose where the device includes an atomizer. However, Hara et al. disclose in the patent entitled "Group of particles for air filter test and method of air filter test" where the device includes an atomizer (Column 7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mihashi to include an atomizer. By adding this feature the

apparatus would be able to produce particles within a particular range of sizes.

8. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mihashi in view of Wadley et al.

Regarding claim 24, Mihashi does not explicitly disclose where the particles are about thirty nanometers to about two microns in size.

However, Wadley et al. disclose in the patent entitled "Production of nanometer particles by directed vapor deposition of electron beam evaporant" where the particles are about thirty nanometers to about two microns in size (Column 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mihashi to include where the particles are about thirty nanometers to about two microns in size. By adding this feature the apparatus would be able to ensure the counting of particles within a particular range.

9. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mihashi.

Regarding claim 30, Mihashi discloses creating an aerosol having physiologically safe polydisperse particles and forcing the aerosol into hollow fiber walls bundled in the dialyzer (Abstract). Mihashi does not disclose rejecting the dialyzer if at least a threshold amount of particles escape through the fiber walls. However, since Mihashi is concerned with leak testing the hollow fiber with the dialyzer the apparatus would be



rejected if there was a leak since it would be deemed nonoperational because there was a significant amount of particles to pass through the walls.

Regarding claim 31, Mihashi discloses the step of pressurizing the aerosol (Figure 1).

10. Claims 9-19,21,23 and 32-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 50-52 are objected to.

12. Claims 41-49 are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to André K. Jackson whose telephone number is (571) 272-2196. The examiner can normally be reached on Mon.-Thurs. 7AM-4PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 2856

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.J.

June 9, 2005

  
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